REMARKS

Claims 1-7 and 20-24 are pending. Claims 1 has been amended. Support for the amended claims can be found throughout the specification, for example, at page 10, lines 5-16 and page 15, line 19 through page 16, line 2, in the sequence listing, and in the claims as originally filed. No new matter enters by way of these amendments.

I. Status

An appeal brief was filed on September 8, 2003 and a copy was filed on November 21, 2003.[1] The Examiner indicates, however, that "[u]pon consideration of the record including arguments in the brief, the claims on appeal, and further review of the prior art, finality of the rejection of the last Office Action (mailed 08 April 2003) is withdrawn." Office Action at page 2. The Examiner further states "that this application is not ripe for appeal as all of the issues have not been developed fully." *Id.* Applicants acknowledge that the finality of the previous Office Action has been withdrawn and that new grounds of rejection have been set forth in the present Office Action.

II. Rejection under 35 U.S.C. § 112, first paragraph – New Matter

Claims 2-3 and 6-7 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

[1] In the Office Action, the Examiner indicates that the copy was filed "on 21 November 2004" which Applicants treat as a typographical error.

time the application was filed, had possession of the claimed invention." Office Action at page 2.

The Examiner alleges that Applicants' previous claim amendment "to indicate that the nucleic acid molecule according to claim 1 'further comprises' an additional element" is new matter. Office Action, page 2. The Examiner contends that "[n]one of the portions of the specification pointed to provide support for these concepts." *Id.*

It is well-established law that use of the transitional term "comprising" or "having" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are <u>not</u> specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head. In addition, the term "comprising" is defined by Section 2111.03 of the M.P.E.P. as synonymous with "including," "containing," or "characterized by," and is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 U.S.P.Q.2d 1608, 1613 (Fed. Cir. 1997); *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 U.S.P.Q.2d 1398, 1410 (Fed. Cir. 1997). Because claims 2-3 and 6-7 as originally filed were "comprising" claims, they did not exclude the possibility of further comprising the additional elements. Moreover, claims 2-3 and 6-7 depend from claim 1, which is directed to "a substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing under conditions of 6.0 X sodium

chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement thereof". Contrary to the Examiner's assertion, the additional elements of each of these claims is not required to be found within SEQ ID NO: 1 or its complement, but rather may be found in a nucleic acid molecule that hybridizes to SEQ ID NO: 1 or its complement under the recited conditions.

Moreover, Applicant maintains that the specification describes these elements. *See, e.g.*, specification at page 1518, line 21 through page 1519, line 5; page 1520, line 1 through page 1522, line 2; and page 1526, lines 1-5. Thus, claims 2-3 and 6-7 as originally filed, along with the specification as originally filed, disclosed all of the elements of the pending claims.

It appears that the Examiner is claiming that the addition of the phrase "further comprising" constitutes new matter because "the amended claims would fairly encompass a sequence fully containing SEQ ID NO: 1 with an additional and unrelated microsatellite sequence (claim 2), with an additional and unrelated region containing a single nucleotide polymorphism (claim 3), and with an additional and unrelated promoter or partial promoter region (claim 6)." Final Action, page 3. Claim 1 as originally filed recites "a substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing to a second nucleic acid molecule having a nucleic acid sequence... of SEQ ID NO: 1..." or complement thereof. Specification, page 1613, lines 2-5. Nowhere in claim 1 or its dependents was it ever recited that the additional elements must be or are contained within SEQ ID NO: 1. The Examiner's interpretation is incorrect and unsupported by the law and the language of the claims as originally filed.

Applicants request reconsideration and withdraw of the 35 U.S.C. § 112, first paragraph rejection of claims 2-3 and 6-7 for new matter.

III. Rejection under 35 U.S.C. § 101

Claims 1-7 and 20-24 stand rejected under 35 U.S.C. § 101 "because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility." Office Action at page 4. Applicants respectfully traverse this rejection.

The rejection is based upon two basic premises. First, the Examiner alleges "[t]here does not appear to be a direct assertion as to how to use SEQ ID NO: 1."[2] Office Action at page 4. Second, the Examiner asserts that further research is required for the uses described in the specification. *Id.,* at page 6.

As the Examiner acknowledges, the "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

[2] Applicants note that SEQ ID NO:1 has occasionally been referred to, by both the Applicants and the Office, as an EST. Applicants note, however, that SEQ ID NO: 1 is isolated from maize genomic DNA and therefor is not an EST sequence.

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, and use in comparative mapping. *See, e.g.*, specification at page 1563, line 8 through page 1571, line 5, and page 1560, line 1 through page 1563, line 7. Either of these utilities described alone is enough to satisfy 35 U.S.C. § 101. Because Applicant need only establish a single utility to satisfy 35 U.S.C. § 101, and because he has done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

The Examiner asserts, however, that "[t]here do not appear to be any particular functional characteristics of the sequence identified." Office Action at page 4. In support of this assertion, the Examiner points to sections of the specification describing that the

SEQ ID NOs encode proteins, are promoters and are markers. The Examiner alleges that "[t]hese are mutually exclusive classes of nucleotide sequences." *Id.* This is incorrect. The Examiner has identified a cursory summary of the invention, however, the specification further describes that the nucleic acid molecules of the present invention can be used as markers and further, a class of the nucleic acid molecules of the present invention comprise promoter or partial promoter regions (*see, e.g.*, specification at page 1526, lines 1-5), and a class of agents of the present invention comprise one or more of the peptide molecules encoded by a nucleic acid molecule, complement of fragment thereof of the present invention (*see, e.g.*, specification at page 1540, lines 16-23). One of ordinary skill in the art can discern from the specification and from the sequence listing the class of nucleotide sequences into which SEQ ID NO: 1 falls. Moreover, a given nucleotide sequence may contain both a promoter sequence and a protein encoding sequence. At the same time, such a nucleotide sequence having both the promoter and encoding sequence can also be used as a marker. As such, they are not "mutually exclusive classes of nucleotide sequences."

In addition, the Examiner asserts that "[a]s the functional identity of SEQ ID NO: 1 speaks to an evaluation of its utility and how to use it, applicant is being deliberately obstructive and misleading in their responses." Office Action at page 5. Applicant knows of no requirement to further delineate SEQ ID NO: 1 and the Examiner has not cited any authority for such a requirement. Contrary to the Examiner's assertion, Applicant has not been "deliberately obstructive or misleading in their responses." Applicant has asserted specific and substantial utilities for the claimed sequence, that is all that is required.

Applicants respectfully submit that the Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). Thus, the utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The law dictates that the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

In addition to the utilities cited above, the specification describes multiple uses for the claimed nucleic acid sequence. *See, e.g.,* specification at page 1546, line 15, *et seq.*, under the heading "Uses of the Agents of the Present Invention." Many of these utilities described alone is enough to satisfy 35 U.S.C. § 101. The Examiner denigrates these utilities because "further research is required for such uses." Office Action at page 6.

Many of the disclosed utilities in this case, including these utilities, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are not "useful" because the specification allegedly "does not disclose whether the claimed nucleic acid molecules can, in fact, be used to detect any polymorphism whatsoever. Thus, the specification leaves open the possibility that there may be no polymorphism to detect." Office Action,

page 9. However, the fact that, for example, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Applicants maintain that use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas. Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage. It is irrelevant that the Applicant "merely isolated [the nucleotide sequences]" rather than "design [them] for any particular purpose." Office Action at page 8. The claimed sequence can still be used to detect the presence or absence of a polymorphism.

The Examiner also asserts that the claimed nucleic acid molecules lack utility apparently because the specification has not identified "any particular polymorphisms associated with a trait or traits, identified any particular promoters or regulatory elements useful in methods of recombinant gene expression, determined that any of the putative open reading frames in the sequence actually encodes a protein having a specific use,

etc." Office Action at page 5. Applicants respectfully submit that the skilled artisan would be able to ascertain these uses and activities based on Applicants' disclosure and tools available to practitioners in the art, *e.g.*, BLASTX. Furthermore, such disclosure is not necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in cosuppression/antisense applications. The claimed sequence has utility even without such disclosure, *e.g.*, of a particular polymorphism associated with a trait or traits. The presence or absence of a polymorphism between two or more populations demonstrates genetic heritage. For example, the absence of a polymorphism usually indicates that the two (or more) populations being compared share a common genetic heritage.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be

provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

The Examiner further alleges that "the specification acknowledges that further analysis is required to determine a use for a polymorphism even assuming one is found." Office Action at page 10. The passage quoted by the Examiner is one of several means in which a polymorphism can be determined. Nowhere does the specification say that "further analysis is required to determine a use for a polymorphism." The Examiner again has not provided any support for the allegation that the claimed sequence cannot be used for the disclosed utilities.

The Examiner also alleges that "[a]pplicant cites *Carl Zeiss Stiftung v. Renishaw PLC* in support of their position that utility has been established." and "applicant mischaracterizes the findings of this decision." Office Action at page 12. Applicants note that the case was not cited in support for the proposition alleged by the Examiner. In fact, the case was not cited at all by the Applicants in either the Amendment and Response to Office Action filed January 7, 2003 or the Appellant's Brief filed September 8, 2003. As such, Applicants made *no* characterization of the findings of that decision.

The Examiner further has again not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re*

Brana, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

IV. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-7 and 20-24 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 17. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement

rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

V. Rejection under 35 U.S.C. § 102(a)

Claims 1-7 and 22-24 stand rejected under 35 U.S.C. § 102(a) as allegedly "being anticipated by Tikhonov et al. (PNAS, 96: 7409-7414, 22 June 1999) ("Tikhonov *et al.*") in view of GenBank Accession No. AF123535." Office Action at page 17.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). In the present application, claim 1 is directed to substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing under recited conditions to a second nucleic acid sequence of SEQ ID NO: 1 or complement thereof. Whatever else Tikhonov *et al.* discloses, it does not disclose a nucleic acid molecule capable of specifically hybridizing under the recited conditions to the complete nucleic acid sequence of SEQ ID NO: 1.

Moreover, claim 21, from which claim 22 depends, is directed to "a substantially purified first nucleic acid molecule comprising a fragment nucleic acid sequence having from about 50 to about 100 nucleotide residues; wherein said fragment nucleic acid sequence exhibits complete complementarity to a second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 or complement thereof." The

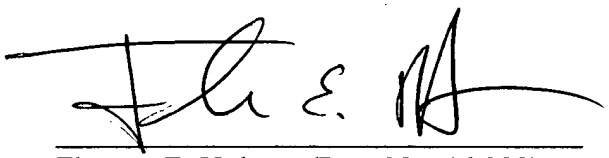
Examiner identifies nucleic acid fragments of 14 nucleotides and 42 nucleotides from the sequence of Tikhonov *et al.* and argues that these fragments anticipate the claims of the present invention. Whatever else Tikhonov, *et al.* discloses, it does not disclose "a substantially purified first nucleic acid molecule comprising a fragment nucleic acid sequence having from about 50 to about 100 nucleotide residues; wherein said fragment nucleic acid sequence exhibits complete complementarity to a second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 or complement thereof."

As such, the presently amended claims are not anticipated by Tikhonov, *et al.* cited by the Examiner. Whatever Tikhonov *et al.* teaches, it does not disclose a nucleic acid molecule capable of specifically hybridizing under the recited conditions to the complete nucleic acid sequence of SEQ ID NO: 1 or a fragment from about 50 to about 100 nucleotide residues with greater than 90% sequence identity to SEQ ID NO: 1. Nor does it disclose a "substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 1 or complement thereof." Absent a teaching of each and every element of the claims, the reference cited by the Examiner does not anticipate claims 1-7 and 22-24 and the rejection should be reversed. To facilitate prosecution, however, claim 1 has been amended to recite "a second nucleic acid molecule having a complete sequence of SEQ ID NO: 1." Accordingly, the rejection of claims 1-7 and 22-24 under 35 U.S.C. § 102(a) is moot. Applicants respectfully request the 35 U.S.C. § 102(a) rejection be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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Thomas E. Holsten (Reg. No. 46,098)
Holly L. Prutz (Reg. No. 47,755)
David R. Marsh (Reg. No. 41,408)

ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004-1206
202.942.5000 telephone
202.942.5999 facsimile

Of Counsel
Lawrence M. Lavin, Jr.
(Registration No. 30,768)
Thomas E. Kelley
(Registration No. 29,938)
Monsanto Company